

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Jeffrey L. Browning et al.

Serial No.: 09/931,402

Filed: August 16, 2001

For: Anti-Lymphotoxin-Beta Receptor Antibodies as

Anti-Tumor Agents

Attorney Docket No.: BINB185CPUSDV

Group Art Unit: 1642

Examiner: YAEN, CHRISTOPHER H

Commissioner for Patents PO Box 1450 Alexandria, Virginia 22313-1450

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Date of Deposit: May 3, 2004	Mailing Label Number: EL 982738090 US
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INFORMATION DISCLOSURE STATEMENT

Dear Sir:

The present application is a Divisional Application of U.S. Serial No. 08/875,560, filed July 25, 1997 (Atty. Docket No. BINB185CPUS). The majority of the references listed on the enclosed PTO Form SB-08 have been previously cited by or submitted to the Office in the prior application and, in accordance with 37 CFR §1.98(d), copies of references A1-B2,

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B4-D6 are not enclosed, but will be provided upon request. The remaining reference B3 has not been previously cited and is enclosed herewith.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed per se as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

In accordance with 37 CFR §1.97(c)(2) and §1.17(p), please charge the \$180.00 submission fee to our Deposit Order Account No. 12-0080. Please charge any necessary additional fees or credit any overpayments to our Deposit Order Account No. 12-0080.

Respectfully submitted, LAHIVE & COCKFIELD, LLP

Cristin E. Howley, Pha. Registration No. 55,281

Agent for Applicants

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Date: May 3, 2004

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Complete if Known
Application Number 09/931,402

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT
First Named Inventor Jeffrey L. Browning
Art Unit 1642

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Examiner Name YAEN, CHRISTOPHER H

U.S. PATENT DOCUMENTS					
Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant
Initials*	No. ¹	Number-Kind Code ² (if known)	MM-DD-YYYY	Applicant of Cited Document	Figures Appear
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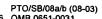
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	FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines,		
	No.1	Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear		
	A1	WO 94/13808 A2	06-23-1994	BIOGEN INC		Г	
	A2	WO 92/00329 A1	01-09-1992	BIOGEN INC		:	

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		NON PATENT LITERATURE DOCUMENTS	
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	А3	Alderson, Mark R., 1994, International Immunology, 6:1799-1806, "Regulation of Apoptosis and T cell activation by Fas-specific mAb".	
	A4	Androlewicz, Matthew, J. of Biological Chem., 1992, 267:2542-2547, "Lymphotoxin Is Expressed as a Heteromeric Complex with a Distinct 33-kDa Glycoprotein on the surface of an Activated Human T Cell Hybridoma".	
	A5	Arulanandam, Antonio R., 1993, J. Exp. Med., 177:1439-1450, "A Soluble Multimeric Recombinant CD2 Protein Identifies CD48 as a Low Affinity Ligand for Human CD2: Divergence of CD2 Ligands during the Evolution of Humans and Mice".	
	A6	Bernstein, David, 1993, Antiviral Research, 20:45-55, "Effects of therapy with an immunomodulator (imiquimod,R-837) along and with acyclovir on genital HSV-2 infection in guinea-pigs when begun after lesion development".	
	A7	Browning, Jeffrey, Androlewicz, Matthew et al., 1991, J. of Immunology, 147:1230-1237, "Lymphotoxin and an Associated 33-kDa Glycoprotein Are Expressed on the Surface of an Activated Human T Cell Hybridoma".	
	A8	Browning, Jeffrey and Douglas, Irene et al., 1995, J. of Immunology, 154:33-46, "Use of Specific Monoclonal Antibodies and Soluble Receptors".	
	A9	Browning, Jeffrey and Ngam-ek, Apinya et al., 1993, Cell, 72:847-856, "Lymphotoxin Beta, a Novel Member of the TNGF Family that Forms a Heteromeric Complex with Lymphotoxin on the Cell Surface".	

Examiner	Date	
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	B1	Browning, Jeffrey and Ribolini, Ann, 1989, J. of Immunol., 143:1859-1867, "Studies on the Differing Effects of Tumor Necrosis Factor and Lymphotoxin on the Growth of Several Human Tumor Lines".	
•	B2	Crowne, Paul, VanArsdale, Todd, et al., 1994, J. of Immunol. Methods, 168:79-89, "Production of lymphotoxin (LTalpha) and a Soluble dimeric form of its receptor using the baculovirus expression system".	
	В3	Browning, J. et al. The 9 th International Congress of Immunology, San Francisco, July 23-29, 1995, "Signalling through the lymphotoxin-beta receptor in conjunction with interferongamma induces the death of a human tumor line.	
	B4	Crowne, Paul, VanArsdale, Todd et al., 1994, Science, 264:707-710, "A Lymphotoxin Beta Specific Receptor".	
	B5	Dhein, Jenset al., 1992, J. of Immunol., 149:3166-3173, "Induction of Apoptosis By Monoclonal Antibody Anti-APO-1 Class Switch Variants Is Dependent On Cross-Linking of APO-1 Cell Surface Antigens".	
	В6	Dighe, Anand et al., 1994, Immunity, 1:447-456, "Enhanced In Vivo Growth and Resistance to Rejection Tumor Cells Expressing Dominant Negative IFNy Receptors".	
	B7	Duzgunes, Nejat et al., 1992, J. of Cell Biochem., 16E:77, "Liposome Targeting To HIV-Infected Cells Via Recombinant Soluble CD4 and CD4-IgG".	
	B8	Eppstein, Deborah, 1985, Proc natl Acad. Sci., 82:3688-3692, "Biological activity of liposome-encapsulated murine interferon y is mediated by a cell membrane receptor".	
·	B9	Fukushima, Keiko et al., 1993, Arch. Biochem. Biophys., 304:144-153, "N- Linked Sugar Chain Structure of Recombinant Human Lymphotoxin Produced by CHO Cells: The Functional Role of Carbohydrate as to Its Lectin-like Character and Clearacne Velocity".	
	B10	Havell, Edward et al., 1988, J. Exp. Med., 167:1067-1085, "The Anittumor Function of Tumor Necrosis Factor(TNF)".	
	B11	Hwang et al., 1980, Pro. Natl. Acad. Sci., 77:4030-4034, "Hepatic uptake and degradation of unilamellar sphingomyelin/cholesterol liposomes: A kinetic study".	
	B12	Johne, Bert et al., 1993, J. Immun.Methods, 160:191-198, "Epitope mapping and binding kinetics of monoclonal antibodies studied by real time biospecific interaction ".	
,	B13	Juraskova, Vera et al., 1992, Eur. J. Pharmacol., 221:107-111, "Interferon inducer, polyribogunanylic polyribocytidylic acid, inhibits experimental hepatic metastases in mice"	
	B14	Kawabe, Tsutomu et al., 1994, Immunity, 1:167-178, "The Immune Responses in CD40- Deficient Mice: Impaired Immunoglobullin Class ".	
	B15	Kolanus, Waldemar et al., 1993, Cell, 74:171-183, "T Cell Activation by Clustered Tyrosine Kinases".	

Examiner	Date	
Signature	 Considered	

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Application Number	09/931,402				
Filing Date	August 16, 2001				
First Named Inventor	Jeffrey L. Browning				
Art Unit	1642				
Examiner Name	YAEN, CHRISTOPHER H				
Attorney Docket Number	BINB185CPUSDV				

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	No. ¹	and/or country where published.	T²
	C1	Kopp, William C. et al., 1993, J. of Immunother., 13:181-190,	
		"Immunomodulatory Effects of Interferony in Patients with Metastatic Malignant	
		Melanoma".	
	C2	Lane, Peter et al., 1992, Eur. J. Immunol., 22:2573-2578, "Activated human T cells express a	
		ligand for the human B cell-associated antigen CD- 40 which participates in T cell-dependent	
		activation of B lymphocytes".	
	C3	Langer, Robert, 1982, Chemtech. 12:98-105, "Controlled release of macromolecules".	
	C4	Langer, Robert, Brem, Henry et al., 1981, J. of Blomed. Materials, 15:267-277,	
		"Biocompatibility of polymeric delivery systems for macromolecules".	
	C5	Ling, Leona et al., 1995, J. of Interferon and Cytokine Res., 15:53-59, "Human Type I	
		Interferon Receptor, IFNAR, Is A Heavily Glycosylated 120- 130 kD Membrane Protein".	
	C6	Loetshcer, Hansruedi et al., 1991, J. of Biolog. Chem., 266:18324-18329, "Recombinant 55-	
	***	kDa Tumor Necrosis Factor (TNGF) Receptor".	10.5
	C7	Morrison, Sherle et al., 1984, Pro. Natl. Acad. Sci., 81:6851-6855, "Chimeric human antibody	
		molecules: Mouse antigen-binding domains ".	
	C8	Niederle, Norbert et al., 1993, Leuk. Lymphoma, 9:111-119, "Long-Term Treatment of	
		Chronic Myaelogenous Leukemia with Different Interferons: Results from Three Studies".	
	C9	Onishi, Tetsuro et al., 1994, Acta. Urol. Jpn., 40:195-200, "A Study On Direct Antitumor	
		Activity of Bropirimine (Oral Interferon Inducer) For Renal Cell Carcinoma".	
	C10	Pleskov, V.M. et al., 1994, pp. 125-128, "Receptor-Mediated Endocytosis of Influenza	
		Viruese and Low Density Lipoproteins by Tissue Cells".	
	C11	Queen, Cary et al., 1989, Proc. Natl. Acad. Sci., 86:10029-10033, "A Humanized antibody	
		that binds to the interleukin 2 receptor".	
	C12	Raitano, Arthur B. et al., 1990, J. of Biol. Chem., 265:10466-10472, "Tumor Necrosis Factor	
		Up-Regulates y-Interferon Binding in a Human Carcinoma Cell Line".	
	C13	Schiller, Joan et al., 1991, Cancer Research, 51:1651-1658, "Biological and Clinical Effects	
		of Intravenous Tumor Necrosis Factor-alpha Administered Three Times Weekly".	
	C14	Schoenfeld, Hans-Joachim et al., 1991, J. of Biol. Chem., 266:3863-3869, "Efficient	
		Purification of Recombinant Human Tumor Necrosis Facotr Beta from Escherichia coli	
		Yields Biologically Active Protein with a Trimeric Structure that binds to Both Tumor	
		Necrosis Factor Receptors".	
	C15	Sidman, Kenneth et al., 1983, Biopolymers, 22:547-556, "Controlled Release of	
		Macromolecules and Pharmaceuticals from Synthetic Polypeptides Based on Glutamic	
		Acids".	

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5	STATEMENT I	3Y /	APPLICANT	First Named Inventor	Jeffrey L. Browning	
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Sheet	4	of	4	Attorney Docket Number	BINB185CPUSDV	

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	D1	Stepushkin, A.N. et al., 1994, pp. 131-134, "Comparative Studies of Live and Inactivated Influenza Vaccines: Organization of the Observations and the Results of Studies of Reactogenicty and Immunogenicity".	
	D2	Traunecker, Andre et al., 1989, Nature, 339:68-70, "Highly efficient neutralization of HIV with recombinant CD4-immunoglobulin molecules".	
	D3	Ullrich, Axel et al., 1990, Cell, 61:203-212, "Signal Transduction by Receptors with Tyrosine Kinase Activity".	
	D4	Winter, Greg el al., 1991, Nature, 349:293-299, "Man-Made antibodies".	
	D5	Xu, Jianchao et al., 1994, Immunity, 1:423-431, "Mice Deficient for the CD40 Ligand".	
	D6	Yonehara, Shin et al., 1989, J. Exp. Med., 169:1747-1756, "A Cell-Killing Monoclonal Antibody (Anti-Fas) To A Cell Surface Antigen Co-Downregulated With The Receptor Of Tumor Necrosis Factor".	

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